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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,502	04/11/2006	Traci Jo Barron	X-16327	3927

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ELI LILLY & COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER	
ANDERSON, MICHAEL J	
ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
05/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,502	BARRON ET AL.	
	Examiner	Art Unit	
	MICHAEL J. ANDERSON	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burroughs (US Patent No. 6,221,046 B1) (Hereafter, Burroughs) in view of Burroughs.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Burroughs (US Patent No. 6,221,046 B1) (Hereafter, Burroughs).

With regards to claim 1, Burroughs discloses (figures 1-15) a medication dispensing apparatus comprising: a housing (22, 24, and 26); an axially extending drive member (38) rotatably and axially fixed within said housing during dose preparing, and rotatably fixed and axially movable in a distal direction relative to said housing during dose injecting, said drive member including a threaded shaft (204); a fluid container defining a medicine-filled reservoir (40) with a movable piston (210) at one end and an outlet at the other end, said piston engagable by said drive member to be advanced toward said outlet when said drive member is moved distally (figures 1 and 2); a nut (36) threadedly engaged with the drive member shaft to be axially movable relative thereto during rotation of said nut relative to said drive member; a nut driver (32 and 34) rotatably and axially shiftable relative to said housing; wherein said nut and said driver include cooperating elements which when engaged rotatably lock together said nut and said driver, and which when disengaged permit relative rotation of said nut and said driver (figure 2); a guide disposed on one of said driver and said housing; a follower disposed on the other of said driver and said housing; wherein said guide an9d follower cooperate to promote a user moving said driver relative to said housing along a travel path that operates the apparatus, said travel path including a dose preparing section and a dose injecting section, said dose preparing section including a reset segment, a nut engaging segment, and a nut rotating segment connected in sequence,

and wherein said injecting section connects said nut rotating segment with said reset segment; wherein said cooperating elements of said nut and said driver are disengaged when said driver is disposed in said reset segment; wherein said cooperating elements of said nut and said driver become engaged when said driver is shifted through said nut engaging segment from said reset segment to said nut rotating segment; wherein the engagement of said cooperating elements of said nut and said driver cause said nut to screw proximally along said threaded shaft when said driver is shifted through said nut rotating segment from said nut engaging segment to said injecting section; wherein when said driver is shifted through said injecting section from said nut rotating segment to said reset segment, said nut and said drive member are shifted in the distal direction to axially advance said fluid container piston to dispense medicine from said outlet, and said cooperating elements of said nut and said driver become disengaged; However, as applicant points out in the 2/13/2008 remarks/arguments, Burroughs separately discloses a hard stop in the travel path. Therefore it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injector of Burroughs as further disclose by Burroughs to move the hard stop the end of the injector to prevent rotation of the driver or dial.

With regard to claim 2 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said nut engaging segment and said dose injecting section of said travel path are oriented in the axial direction.

With regard to claim 3 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said reset segment of said travel path is oriented generally transverse to said axial direction.

With regard to claim 4 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said nut rotating segment of said travel path is helically oriented.

With regard to claim 5 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said travel path involves both 360 degrees of rotation of said driver and an equal amount of distal and proximal travel of said driver, whereby said driver, at the end of an injection, has the same axial position and same rotational position as at the end of the prior injection, and wherein said guide includes a second hard stop for said follower to define a second end of said reset segment of said driver travel path, which second hard stop prevents rotation of said driver in one direction after the end of the injection by abutment by said follower.

With regard to claim 6 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein along said injection section of said travel path, said guide comprises first and second surfaces that define a channel in which said follower is slidable, said surfaces during injecting serving as physical stops to prevent rotation of said nut driver by abutment by said follower until an injection is complete, thereby limiting misuse of the apparatus.

With regard to claim 7 Burroughs discloses the medication dispensing apparatus of claim 6 and further discloses (columns 5 and 6) wherein along said nut rotating

segment of said travel path, said guide comprises third and fourth surfaces that define a channel in which said follower is slidable, said third surface providing a distal barrier during nut rotating that prevents distal plunging of said driver by abutment by said follower until said follower passes from said nut engaging segment to said injecting section, thereby limiting misuse of the apparatus.

With regard to claim 8 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said follower comprises an outward projection formed on said driver, said outward projection being radially fixed at all times during pen use.

With regard to claim 9 Burroughs discloses the medication dispensing apparatus of claim 8 and further discloses (columns 5 and 6) wherein said guide comprises a projecting rib formed on said housing and that extends continuously around an interior surface of said housing.

Response to Amendment

The present communication responds to the Amendment of 2/13/2008. By this communication, no claims were amended. The amendments did not add new matter. Claims 1-9 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments, see pgs 5 and 6, filed 2/13/2008, with respect to the rejection(s) of claim(s) 1-9 under 102(b) have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Burroughs.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that the driver is not in the reset segment, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ANDERSON whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Anderson/
Examiner
Art Unit 3767

MJA
5/11/2008
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767